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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,735	06/15/2001	Eric F. Fisher	02,006; A-415H	1579
20306	7590	11/13/2003	EXAMINER	
MCDONNELL BOEHNEN HULBERT & BERGHOFF 300 SOUTH WACKER DRIVE SUITE 3200 CHICAGO, IL 60606			O HARA, EILEEN B	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/882,735

Applicant(s)

FISHER ET AL.

Examiner

Eileen O'Hara

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,22-25,28 and 31-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10,22-25,28 and 31-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1, 2, 4-10, 22-25, 28 and 31-44 are pending in the instant application. Claims 1, 2, 4-10, 22-25, 28 and 31 have been amended, claims 3, 11-21, 26, 27, 29 and 30 have been canceled and claims 32-44 have been added as requested by Applicant in the Paper filed August 25, 2003. All pending claims are currently under examination.

Priority

2. Applicants' amendment to the specification to update the priority is acknowledged.

Withdrawn Objections and Rejections

3. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 31, 34, 36, 38 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4.1 Claims 31 and 43 are vague and indefinite because they are incomplete kit claims. The kits comprise a sTNFR molecule and a second container having a physiologically acceptable

solvent, but there is no recitation of a first container. It is suggested the phrase “a first container containing” be inserted after the word “comprising” in the claims.

4.2 Claims 34, 36 and 38 are vague and indefinite because they encompass a sTNFR that is produced by a nucleic acid that hybridizes to the complement of the recited nucleic acid molecules. Though the specification on pages 46-47 describes various hybridization and wash conditions, they are exemplary. The term “hybridizes” is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. This rejection could be overcome by recitation of specific hybridization and wash conditions described in the specification.

4.3 Claims 34-39 are vague and indefinite because they encompass the recited polypeptides or polynucleotides encoding the polypeptides **“or portions thereof”** of the polypeptides or polynucleotides, and there is no definition of how big a portion would be or what activity it would have. The rejection could be overcome by a limitation in the claims that the polypeptide would bind TNF α .

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5.1 Claims 1, 2, 4-10, 22-25, 28, 31-34 remain rejected and new claims 40-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The

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claims had been rejected because of the recitation of “variants or derivatives thereof”.

Applicants have amended the claims to delete “variants or derivatives thereof”, and have overcome the rejection based on this. However, Applicants have amended the claims to include the new limitation of “with at least one amino acid substitution”, and the claims are now rejected because of this limitation.

The specification describes a polypeptide sequence consisting of SEQ ID NO: 2, and truncation variants thereof, which are soluble truncated forms of TNFR 1, and shown to have the activity binding tumor necrosis factor α . However, the claims as written include polypeptides comprising fragments and homologues, encompass polypeptides that vary substantially in length and also in amino acid composition. As written, because there is no limit to the number of amino acid substitutions, the claims encompass a protein that can bind tumor necrosis factor α , but can have an amino acid sequence that could be completely different (see rejection under 35 U.S.C. 102). The instant disclosure of a single polypeptide, that of SEQ ID NO: 2 and truncation variants with the instantly disclosed specific activity, does not adequately support the scope of the claimed genus, which encompasses a substantial variety of subgenera. A genus claim may be supported by a representative number of species as set forth in *Regents of the University of California v Eli Lilly & Co*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention”. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”) Thus, an applicant complies with the

written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the ‘525 patent, “requires a precise definition, such as by structure, formula, chemical name, or physical properties,” not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, “an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.” Id at 1170, 25 USPQ2d at 1606.”

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. The instant specification discloses, however, a single isolated polypeptide sequence SEQ ID NO: 2 and truncation variants. There is no structure required. Given the fact that the specification fails to provide objective evidence that the additional sequences are indeed species of the claimed genus it cannot be established that a representative number of species have been disclosed to support the genus claim. The instantly claimed genus is not so limited and the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polynucleotides encompassed.

Claims 1, 2, 4-10, 22-25, 28, 31-34 and 40-44 are also rejected under 35 U.S.C. 112, first paragraph, because claims 1 and 2 are single means claims, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth

rejection under 35 U.S.C. 112, first paragraph. In re Hyatt , 708 F.2d 712,>714 - 715,< 218 USPQ 195>, 197< (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.). When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See M.P.E.P. 2164.08(a).

5.2 Claims 24, 25 and 36-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical compositions comprising the recited polypeptides that are recombinantly produced and that are isolated from host cell or nutrient medium, does not reasonably provide enablement for polypeptides that are recombinantly produced and that are not isolated from host cell or nutrient medium. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Claims 24, 25 and 36-39 recite that the recombinantly produced polypeptides may “optionally” isolated from the host cell or nutrient medium. However, it is not an art accepted practice to administer a pharmaceutical composition comprising a polypeptide that has not been isolated from the recombinant cell producing it or from the nutrient medium it is produced in. Administration of recombinant host cells or nutrient medium would result in undesirable immunological responses. Deletion of the word “optionally” in the claims would therefore obviate the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al., Science, Vol. 248, pages 1019-1023, 1990.

Claims 1 and 2 encompass a truncated sTNFR polypeptide comprising the sequences recited in the claims, wherein the protein can have at least one amino acid substitution.

Smith et al. disclose the TNF α receptor II, and extracellular (soluble) domain (Figure 3). As written, because there is no limit to the number of amino acid substitutions, the claims encompass a truncated protein comprising an amino acid sequence that can bind tumor necrosis factor α , but can have an amino acid sequence that could be completely different. Smith et al. meets the limitations of the claims because it discloses a soluble protein that can bind TNF α , and as the claims are written, there is no structural requirement for the protein.

Conclusion

7. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

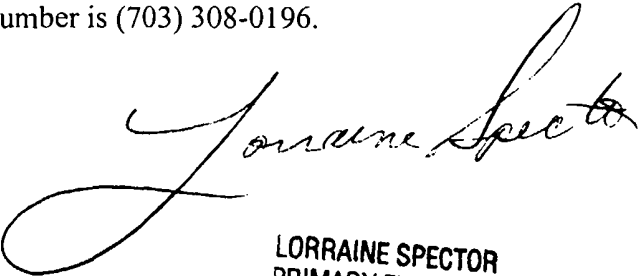
Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner


LORRAINE SPECTOR
PRIMARY EXAMINER